REGULATORY GUIDE B4

COMPLYING WITH TITLE B – FACILITIES UTILIZING ANALYTICAL OR INDUSTRIAL X-RAY EQUIPMENT

South Carolina Department of Health and Environmental Control

October 12, 2004

TABLE OF CONTENTS

REGULATORY GUIDE B4
COMPLYING WITH TITLE B - FACILITIES UTILIZING ANALYTICAL OR INDUSTRIAL X-RAY EQUIPMENT

Each facility that is registered with the Department is required to comply with Regulations 61-64, X-Rays (Title B), which are the regulations concerning x-ray equipment. This guide is intended to assist facilities using industrial and analytical x-ray equipment in complying with Title B regulations.

ANALYTICAL VS. INDUSTRIAL X-RAY EQUIPMENT

The regulations are different for analytical and industrial units. It is important to identify your equipment type. X-ray equipment located at industrial settings usually falls into two types - industrial or analytical. Industrial x-ray equipment is defined as equipment that is used to look at the macroscopic structure of a material, while analytical x-ray equipment is defined as equipment used to look at the microscopic or elemental composition of a material. Examples of industrial x-ray units include: cabinet x-ray units, shielded room radiography, field radiography, irradiators, and x-ray gauges. Industrial units are typically used to look for voids in manufactured material, or the presence of metallic items in a material. Examples of analytical x-ray units include diffraction units, x-ray fluorescence units, and electron microscopes. Analytical units are typically used to look for a particular element, such as iron or lead, in a material. Analytical units may be located in an industrial setting, just as industrial units may be located in an academic setting. The designations of industrial and analytical are for the type of analysis the unit does, not the location of the unit. You may contact this Department with any questions in determining a unit type. Throughout this regulatory guide, the regulations are specified as applying to industrial or analytical units.

GENERAL REQUIREMENTS FOR INDUSTRIAL AND ANALYTICAL EQUIPMENT

Facility Registration Approval (See RHB 2.4)

Prior to installation the facility must submit the following information to the Department:

- Facility name, location address, and mailing address.
- The name of the Radiation Safety Officer (RSO), who is responsible for radiation protection, and the individual's qualifications to serve in this capacity.
- Type and make of x-ray equipment to be installed.
- Operating policies and procedures. See below under "Operating Procedures".
- A training plan. See below under "Training Plan".
- A shielding plan, if required.
- Shielding plan review fees must accompany the shielding plan. ($62.50)
- There is a $62.50 non-refundable fee required for registration of new facilities. The application fee must be submitted with the facility registration approval request.

After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

Registering Equipment (See RHB 2.5)

All x-ray equipment must be registered with the Department. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also required to report, in writing, any changes that affect his x-ray facility or the x-ray equipment. This includes change of location or mailing address, change of Radiation Safety Officer, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan, and any changes in the approved training plan or operating procedures.

Personnel Monitoring (See RHB 3.12)

Personnel monitoring is required in the following situations:

a) When an employee is likely to receive greater than 10% of their occupational dose limit for the year.
b) When an employee under 18 years of age, or a declared pregnant woman, is likely to receive greater than 10% of their applicable dose limit.
c) Finger or wrist dosimetric devices are required of analytical operators using open-beam configuration systems without a safety device, and personnel maintaining analytical equipment if the maintenance procedures requires the presence of a primary beam when any component is disassembled or removed.
d) Personnel monitoring is required for all operators of industrial x-ray equipment. For shielded room radiography, personnel monitoring devices are also required for workers who make "set-ups" and maintenance personnel. During field radiography, a pocket dosimeter or pocket chamber must also be worn.
e) When an individual enters a high radiation area.
f) When the Department deems that it is necessary.

The personnel monitoring devices used to determine compliance with occupational dose limits must be processed by a vendor which possesses current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST). The accreditation must be for the type of radiation for which the individual wearing the device is monitored.

Each registrant must maintain records showing the radiation exposure for each person that is monitored. The records must be preserved indefinitely, or until the Department authorizes their disposal. The records may be maintained on microfilm or other archival media.

Prior Occupational Exposure

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the worker had no prior occupational dose during the current year or states the nature and amount of any prior occupational dose during the current year. The registrant must also attempt to obtain the records of lifetime cumulative occupational radiation dose. The registrant must maintain these written statements until the Department authorizes their disposition.

Occupational Exposure at Multiple Facilities (See RHB 3.4.4)

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any facility must be recorded by each facility at which the employee works. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be

worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

Overexposures (See RHB 3.25)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The registrant is also required to report any radiation levels in an unrestricted area that are in excess of 10 times any limit in the regulations. The time frame for reporting overexposure depends on the exposure that an individual receives. Immediate, 24 hour, and/or twenty day written notification may be required. See RHB 3.25 concerning radiation levels and the requirements for reporting.

Radiation Survey Instruments (See RHB 7.7 for Analytical or RHB 8.4 for Industrial)

All radiation survey instruments used in the surveys and tests listed below must be properly calibrated. With the exception of instruments used in field radiography, the calibration must be performed at intervals not to exceed 12 months and after each instrument servicing. For instruments used in field radiography, calibrations must be performed at intervals not to exceed 3 months. The calibration should be traceable to within 20 percent of the national standard, and performed at two or more points, other than zero, on each scale that are separated by at least 50%. The instrument must be capable of measuring radiation in the energy range(s) and at the dose rates expected to be encountered. Instrument calibration records must be maintained at the facility for review by the Department.

Training Plan (See RHB 7.8 for Analytical or RHB 8.7 for Industrial)

Each facility is required to ensure that all Radiation Safety Officers and x-ray operators are adequately instructed in safe operating procedures and competent in the safe use of the equipment. Each RSO and operator is also required to have instruction in specific areas. The Department will assess RSO and operator training by reviewing the training plan of each facility. Therefore, each facility must establish a training plan to ensure instruction in the areas specified in the regulations. The training plan must document the following items:

1) The topics to be covered during the training period. According to regulations the following items must be addressed as a minimum:

    a) Identification of radiation hazards associated with the use of the equipment.

    b) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases.
    b) Proper operating procedures for the equipment.

    c) The operation, calibration, and limitations of radiation survey instruments. (If required by the employee's position) Proper survey techniques.

    d) Characteristics of x-radiation.

    e) Units of radiation dose. Methods of controlling radiation dose, such as time, distance, and shielding.

f) Personnel monitoring and the use of personnel monitoring devices.

g) Symptoms of acute localized exposures. Proper procedures for reporting an actual or suspected exposure.

i) Applicable State regulations.

These topics are the minimum required subjects that must be covered in operator training. They are not necessarily complete for all facilities. Each facility must assess the type of equipment at their facility, and tailor their training program appropriately.

2) Methods for documenting the training that each operator has received and methods for documenting operator competence. Records must be maintained of all training provided to each operator. The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

Records

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

- Records showing receipt, transfer, use, storage, and disposal of all sources of radiation. (RHB 1.10.1)
- Records showing model and serial numbers of all tubes and controls (RHB 1.10.2.1)
- Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services. (RHB 1.10.2.4)
- Copies of all correspondence with the Department. (RHB 1.10.2.5)
- Records of prior occupational dose for employees. (RHB 3.20)
- Records of personnel monitoring results. (RHB 3.22)
- Records of alterations of safety devices - analytical. (RHB 7.3.5.1.4)
- Records of testing of safety devices - analytical. (RHB 7.6.4)
- Records of surveys, tests, and inspections. (RHB 7.6.2 or 8.9.1)
- Calibration records for survey instruments. (RHB 7.7.3 or 8.4.1.2)
- Records of personnel instruction and competency testing. (RHB 7.8.2 or 8.7.2.4)
- Utilization logs for field radiography. (RHB 8.13.3.1)

· Records from pocket dosimeters for field radiographers. (RHB 8.13.3.8.4)

ANALYTICAL X-RAY EQUIPMENT REQUIREMENTS

Requirements for Operating Procedures (See RHB 7.8.3)

Facilities using analytical x-ray units are required to have written operating procedures. The operating procedures must be available to all workers using the unit. The equipment cannot be operated in any manner except for that specified in the operating procedures. The procedures should include the following items:

1) **Methods and occasions for conducting radiation surveys.**

2) **Methods for controlling access to radiographic areas.**

3) **Methods for locking and securing the x-ray unit.**

4) **Personnel monitoring.** (See page 4)

5) **Maintenance of records.** (See page 6)

6) **Pregnant Employees.**

7) **Training Plan.** (See page 5)

Methods and Occasions for Conducting Radiation Surveys (See RHB 7.6.2)

Analytical x-ray units must have the surveys performed in the following situations:

1) Upon installation of the equipment and at least every twelve months after that.

2) Following any change in the initial arrangement, number, or type of local components in the system.

3) Following any change in operating parameters.

4) Following any maintenance requiring the disassembly or removal of a local component in the system.

5) During the performance of maintenance and alignment procedures if the procedures required the presence of a primary x-ray beam when any local component in the system is disassembled or removed.

6) Any time a visual inspection of the unit reveals an abnormal condition.

7) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

Records of these surveys must be maintained for review by this Department.

Tests of Safety Devices (See RHB 7.6.4)

Tests of safety devices such as interlocks, shutters, and warning lights are required to be conducted on an annual basis. Records of these tests are required to be maintained for inspection by this Department.

Posting and Labeling (See RHB 7.3.2 and 7.3.3)

All facilities must post a "Notice to Employees" in a location where it can be reviewed by all workers. Please contact the Department if you need a copy of this form.

All analytical units must meet the following posting and labeling requirements:

1) Each area or room containing an analytical x-ray unit must be conspicuously posted with a sign or signs bearing the standard radiation symbol and the words "CAUTION - X-RAY EQUIPMENT," or words having similar intent.

2) A label bearing the words "Caution - Radiation - This equipment produces radiation when energized" or words having a similar intent must be placed near any switch which energizes a tube.

3) A sign bearing the words "Caution - High Intensity X-ray Beam," or words having a similar intent must be placed in the area immediately adjacent to each tube head. The sign must be placed so that it is clearly visible to any person operating, aligning, or adjusting the unit, or handling or changing a sample.

Additional Analytical Equipment Requirements

1) Electron microscopes. Electron microscopes are required to be registered with the Department. The only requirement for electron microscopes is that they be installed, shielded, and operated in such a manner that radiation dose limits are not exceeded. They are exempt from all other requirements. (See RHB 7.2)

2) Warning lights are required for all analytical units. They must be located near any switch that energizes an x-ray tube. They must also be illuminated only when the tube is energized, and be fail-safe. (See RHB 7.3.4)

3) Unused ports on x-ray tube housings shall be secured in the closed position to prevent accidental opening. (See RHB 7.3.5.5)

4) All open beam configuration units must have a safety device to prevent entry into the primary beam path. An operator must be in immediate attendance at all times when the equipment is in operation. X-ray tube status and shutter status must be indicated. (See RHB 7.4.1)

INDUSTRIAL X-RAY EQUIPMENT REQUIREMENTS

Requirements for Operating Procedures (See RHB 7.3.4)

Facilities using industrial x-ray units are required to have written operating and emergency procedures. The operating procedures must be available to all workers using the unit. The equipment cannot be operated in any manner except for that specified in the operating procedures. The procedures are required to include the following items:

1) **Methods and occasions for conducting radiation surveys.** (See page 10)

2) **Methods for controlling access to radiographic areas.**

3) **Methods for locking and securing the x-ray unit.**

4) **Personnel monitoring.** (See page 4)

5) **The proper handling of exposed personnel.**

6) **Minimizing exposure of individuals in the event of an accident.**

7) **The procedure for notifying proper persons in the event of an accident.** This must include the listing of names, addresses, and telephone numbers. (See page 5)

8) **Maintenance of records.** (See page 6)

9) **Pregnant Employees.**

10) **Training Plan.** (See page 5)

Methods and Occasions for Conducting Area Surveys

Industrial x-ray units are subject to the following requirements:

1) All industrial x-ray units must be checked for obvious defects at the beginning of each day of equipment use. At least yearly, components associated with radiation safety, such as interlocks or alarm systems, must be inspected for proper functioning. If any component is determined to be damaged, the unit shall not be used until it is repaired. (See RHB 8.9)

2) Cabinet X-ray units cannot be operated until a radiation survey has been performed. The unit and the area adjacent to the unit must be surveyed at least annually after the unit has been put into use. Surveys must also be performed after any repair, modification, or maintenance on the system. (See RHB 8.13.1)

3) Industrial units used in shielded room radiography and field radiography must be surveyed prior to each entry into the radiation exposure area to ensure that the unit is off. The survey must be performed with an instrument capable of measuring radiation of the energies and dose rates to be encountered. (See RHB 8.13.2.2 and RHB 8.13.3.7.1)

Tests of Safety Devices (See RHB 8.13.1.2)

Tests of safety devices such as interlocks, shutters, and warning lights are required to be conducted on an annual basis. Records of these tests are required to be maintained for inspection by this Department.

Posting and Labeling (See RHB 8.13.1.10)

All facilities must post a "Notice to Employees" in a location where it can be reviewed by all workers. Please contact the Department if you need a copy of this form.

Industrial units must meet the following posting and labeling requirements:

1) A label which reads, "CAUTION - RADIATION - This equipment produces radiation when energized," shall be located near or adjacent to each switch that controls the production of x-rays.

2) Cabinet x-ray units must meet these requirements:

   a) Indicators of x-ray production must be legibly labeled "X-RAY ON."

   b) Each port of entry into a cabinet x-ray system must have a clearly legible and visible label bearing the statement: "CAUTION - DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED -- X-RAY HAZARD."

Additional Requirements for Industrial X-ray Equipment

1) Each x-ray machine must be provided with a locking device to prevent unauthorized or accidental production of radiation. The device must be kept locked at all times except when under the direct supervision of a radiographer, radiographer's assistant, radiation safety officer, or an operator. (See RHB 8.2)

2) Cabinet x-ray units. Cabinet x-ray units must have a permanent floor, or be permanently attached to a support system. It must not be possible to insert any body part into the primary beam. The door of the cabinet must have at least two safety interlocks. (See RHB 8.13.1 for additional requirements.)

3) Baggage checkers. Baggage checkers must ensure operator presence at the control area in a position which allows surveillance of the ports and doors during x-ray generation. (See RHB 8.13.1.11)

4) Shielded room radiography. Shielding plans must be submitted and approved by the Department prior to use of the equipment. A radiation area survey must be performed by a Class IX vendor, registered with the Department, within 30 days of installation. This survey must be submitted to this Department for review. See regulatory guide B6 for assistance. (See RHB 8.13.2)

5) Field radiography. Field operations requires the use of a utilization log that includes a description (or make and model number) of the x-ray unit, the identity of the radiographer, the plant or site where it is used, and the dates each radiation machine is used and the number of exposures made. See RHB 8.13.3 for additional requirements. (See RHB 8.13.3)

6) X-ray gauges. (See RHB 8.13.4 for requirements.)

INSPECTIONS

The Department conducts routine periodic inspections of x-ray facilities, on a priority system based on the type of facility that is operating. The Department will also conduct inspections if a complaint is received, or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. Generally, the Department will send a Notice of Inspection letter to a facility about two weeks in advance of the inspection. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. The Department does have the right to make unannounced inspections.

The inspection consists of checking the operation of the x-ray equipment, as well as checking administrative items such as records. Generally, an inspection requires use of the x-ray equipment for about one hour per control. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. Having this information readily available at the time of inspection will greatly facilitate the inspection process.

After a facility is inspected, the inspector will conduct an exit interview. The inspector will discuss any items of noncompliance, as well as any other items that the inspector deems relevant. The inspector will leave an inspection report at the conclusion of the inspection. The inspection report will cite any violations of the regulations. The inspector may also make recommendations concerning the x-ray equipment or the facility itself. A facility representative must sign the inspection report acknowledging receipt of the report. All violations are required to be corrected within 60 days of the inspection.

There may be some inspections which may require additional information be fore they are completed. In these situations, the inspector will send a written report to the facility within approximately two weeks of the inspection. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate that corrective action will be taken to correct any violations that were found upon inspection. The Department will respond, in writing, to the twenty day notification, and will give a date by which all corrections must be made. The facility must notify the Department, in writing, by this date that corrections have been made.

The facility has the option of correcting recommendations. Each violation and recommendation must be addressed individually. Corrective action must be described for each violation and recommendation. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state that in their response. After the Department has received the sixty day notification and reviewed the corrective action, a Completed Corrective Action letter will be sent to the facility.

QUESTIONS

If you have questions, please feel free to call or write:

S.C. DHEC
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
Fax: (803) 545-4412

Regulatory Guides

B1 - Registration of X-ray Facilities and Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B – Facilities Utilizing Analytical or Industrial X-ray Equipment
B5 - Vendor Registration and Responsibilities
B6 - Shielding Plans
B7 - Complying with Title B - Mammography
B8 – Complying with Title B – Bone Densitometry
B9 – Complying with Title B – Veterinary

Visit our web site at : www.scdhec.net

CHECKLIST FOR DHEC INSPECTION

Please have available the following records for the DHEC inspector:

_____ Personnel monitoring reports.

_____ Records of previous occupational dose for employees.

_____ Training plan.

_____ Documentation of operator training.

_____ Records from testing x-ray system performance, including calibration and service records, as well as in-house testing. Records from surveys, tests, and inspections.

_____ A list of all operators of the x-ray equipment. This includes routine operators, as well as back-up operators and part-time operators. Indicate on the list the title of each operator, such as quality control tech, etc. List the number of years experience taking x-rays that each operator has.

_____ Operating procedures.

_____ Utilization logs.(for field radiography)

_____ Instrument calibration records.

Please be familiar with, and be prepared to show the DHEC inspector the following items:

_____ Posted radiation area signs.

_____ Posted "Notice to Employees"

Other questions the inspector will ask:

1) Who does servicing on the x-ray equipment?